DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 25, 2017

Medical Components, Inc. (dba Medcomp)
Courtney Nix
Regulatory Affairs Manager, North America and Europe
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K170770
Trade/Device Name: CT Midline
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: PND
Dated: July 5, 2017
Received: July 6, 2017

Dear Courtney Nix:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S

for
Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
N/A - Unknown

K170770

Device Name
CT Midline

Indications for Use *(Describe)*

The CT Midlines are indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 6 510(k) SUMMARY Traditional 510K

A. **Submitter Information:**

Submitter:	Medcomp® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201, x 2285 Fax: (215) 256-9191
Registration Number:	2518902
Contact:	Courtney Nix Cnix@Medcompnet.com Regulatory Affairs Manager: North America and EU
Date Prepared:	03/13/2017

B. **Proposed or Subject Device Information:**

Trade Name:	CT Midline
Device:	Midline Catheter
Product Code:	PND
Regulation Description:	Intravascular Catheter
C.F.R. Section:	880.5200
Class:	II
Regulation Medical Specialty and Review Panel:	General Hospital

B. **Predicate Device Information:**

510(k) Number:	K141151
510(k) Holder:	Medcomp®
Trade Name:	CT Midline
Device:	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Product Code:	LJS

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Regulation Description:	Percutaneous, implanted, long-term intravascular catheter
C.F.R Section:	880.5970
Class:	II
Regulation Medical Specialty and Review Panel:	General Hospital

D. **Purpose for Submission:**

The purpose of this submission is to remove a contraindication that was once cited in the *Journal of Infusion Nursing* but has since been revised.

E. **Device Description:**

The CT Midline Catheter is designed for peripheral vein catheterization and power injection of contrast media. The lumen is an open-ended design comprised of a soft radiopaque polyurethane material with barium sulfate for radiopacity. The lumen is connected to the extensions via a soft pliable hub with suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid contamination. Female luer connectors provide the connection for intravenous administration.

The CT Midline Catheter is available in a 4Fx20cm single-lumen, or 5Fx20cm double-lumen configuration. The outside diameter of the lumen has a reverse taper increasing gradually near the hub to aid in kink resistance and to provide a mechanical obstruction to bleeding from the venotomy. The lumen has depth marks every centimeter and numerical marks every fifth centimeter. The CT Midline is packaged sterile with the necessary accessories to facilitate insertion.

G. **Indications for Use:**

The CT Midlines are indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

H. **Intended Use:**

The CT Midlines are indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media.

I. **Comparison to Predicate Devices:**

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The proposed CT Midline is substantially equivalent to the predicate device, CT Midline (K141151), in all aspects, including but not limited to, indications for use, intended use, anatomical location, basic design, dimensions, lengths performance, biocompatibility, materials, manufacturing process and method of sterilization. All technology, including features, materials, and principles of operation are identical to what was cleared in K141151, CT Midline. The only difference between the predicate and the proposed device is a revision to the instructions for use (labeling). This revision is to remove a contraindication. The revision to the labeling does not change the intended use of the device, both revisions are in are in alight with the *Journal of Infusion Nursing*.

The difference or changes between the proposed CT Midline and the predicate, CT Midline (K141151), is that the revision to the instructions for use, below is a comparison matrix demonstrating substantial equivalence.

Table 5.1: 510(K) Summary: Design Comparison Matrix

Device	Proposed Device: CT Midline	Predicate Device: CT Midline (K141151)	Substantially Equivalent Comparison
Dimensions or Lengths	Lumen: 4F Single and 5F Double Lumen Length: 20cm	Lumen: 4F Single and 5F Double Lumen Length: 20cm	**Identical, no change**
Indications for Use	The CT Midlines are indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.	The CT Midlines are indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.	**Identical, no change**
Sterilization Method	ETO	ETO	**Identical, no change**
Materials and Processes	LUMEN: Tecothane HUB and SUTURE WING: Pellethane LUERS: Isoplast EXTENSIONS: Pellethane CLAMPS: Acetal Purple: single lumen Purple: double lumen I.D. RING: Lustran	LUMEN: Tecothane HUB and SUTURE WING: Pellethane LUERS: Isoplast EXTENSIONS: Pellethane CLAMPS: Acetal Purple: single lumen Purple: double lumen I.D. RING: Lustran	**Identical, no change**
Performance Testing	Power Injection: 5cc/sec (4F)	Power Injection: 5cc/sec (4F)	**Identical, no change**

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	7cc/sec (5F)	7cc/sec (5F)	

J. **Bench / Performance Data / Non-Clinical Testing:**

No performance testing was required for the revision to the instructions in conjunction with the substantial equivalence claims, effectively demonstrate the proposed device, CT Midline, is equivalent to the predicate device, CT Midline (K141151).

K. **Biocompatibility:**

Biocompatibility was performed on the CT Midline in accordance with ISO 10993-1. According to ISO 10993-1 the final, finished 5F Double lumen CT midline was tested as an implant device with blood contact and prolonged contact duration (greater than 24 hours less than 30 days). Biocompatibility was performed on the finished and sterilized device in accordance with ISO 10993-12:2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials, and 21CFR, Part 58 – Good Laboratory Practices for Nonclinical Laboratory Studies by a contracted laboratory that is ISO 17025 certified.

L. **Summary of Substantial Equivalence:**

The proposed CT Midline is substantially equivalent to the predicate device, CT Midline (K141151), in all aspects, including but not limited to, indications for use, intended use, anatomical location, basic design, dimensions, lengths performance, biocompatibility, materials, manufacturing process and method of sterilization. The only difference between the predicate and the proposed device is a revision to the instructions for use (labeling). This revision is to remove a contraindication.

The proposed device, CT Midline, meets the performance criteria of design verification as specified by ISO standards, guidance documents and internal test protocols. The proposed device is substantially equivalent to the indicated legally marketed predicate as defined in paragraph above.